



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61F 2/02	A1	(11) International Publication Number: WO 98/35632 (43) International Publication Date: 20 August 1998 (20.08.98)
<p>(21) International Application Number: PCT/US98/03066</p> <p>(22) International Filing Date: 13 February 1998 (13.02.98)</p> <p>(30) Priority Data: 60/038,379 13 February 1997 (13.02.97) US</p> <p>(71) Applicant (for all designated States except US): BOSTON SCIENTIFIC IRELAND LIMITED, BARBADOS HEAD OFFICE [IE/BB]; St. Michael, Barbados (BB).</p> <p>(72) Inventors; and (75) Inventors/Applicants (for US only): GELLMAN, Barry, N. [US/US]; 19 Pebble Brook Road, North Easton, MA 02356 (US). MARTIN, William [US/US]; 56 Winterberry Drive, Franklin, MA 02038 (US). RACKLEY, Raymond [US/US]; Apartment #305, 13660 Fairhill, Shaker Heights, OH 44120 (US).</p> <p>(74) Agent: ALTMAN, Daniel, E.; Knobbe, Martens, Olson and Bear, LLP, 16th floor, 620 Newport Center Drive, Newport Beach, CA 92660 (US).</p>	<p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p>Published With international search report.</p>	
(54) Title: STABILIZATION SLING FOR USE IN MINIMALLY INVASIVE PELVIC SURGERY		
<p>The diagram shows a perspective view of a stabilization sling (10). It is an elongated, roughly rectangular shape with rounded corners. A central portion (12) is indicated by dashed lines. Two end portions, (14) on the left and (16) on the right, are shown. Each end portion contains a circular suture receiving site (18). The entire sling is covered with a pattern of small dots, representing a mesh or porous material. Labels 12, 14, 16, and 18 point to their respective parts.</p>		
<p>(57) Abstract</p> <p>The present invention relates to prefabricated urethral suspension slings (10), methods of making the slings, methods of attaching suture to the slings, kits comprising the slings, and methods of using the slings to treat urinary incontinence. The slings (10) comprise a biocompatible material having an elongate shape adapted for urethral suspension. The material has a central portion (12) extending longitudinally between a first end portion (14) and a second end portion (16). Each end portion (14, 16) of the sling (10) contains at least one suture receiving site (18). The suture receiving sites (18) are formed prior to surgery and may be reinforced through a variety of means. Sutures (36) may be attached to the suture receiving sites (18) during the manufacturing process or by the physician prior to or during surgery. Additionally, the end portions (14, 16) of the sling (10) containing the suture receiving sites (18) may be thicker than the central portion (12) of the sling.</p>		

BEST AVAILABLE COPY

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

STABILIZATION SLING FOR USE IN MINIMALLY INVASIVE PELVIC SURGERY

Field of the Invention

The present invention relates to slings for use in improving urinary continence. More particularly, the present invention relates to prefabricated urethral stabilization or suspension slings, methods of making the slings and kits including the slings.

Background of the Invention

Urinary incontinence is a widespread problem in the United States and throughout the world. Urinary incontinence affects people of all ages and can severely impact a patient both physiologically and psychologically.

In approximately 30% of the women suffering from urinary incontinence, incontinence is caused by intrinsic sphincter deficiency (ISD), a condition in which the valves of the urethral sphincter do not properly coapt. In approximately another 30% of incontinent women, incontinence is caused by hypermobility, a condition in which the muscles around the bladder relax, causing the bladder neck and proximal urethra to rotate and descend in response to increases in intraabdominal pressure. Hypermobility may be the result of pregnancy or other conditions which weaken the muscles. In an additional group of women with urinary incontinence, the condition is caused by a combination of ISD and hypermobility.

In addition to the conditions described above, urinary incontinence has a number of other causes, including birth defects, disease, injury, aging, and urinary tract infection.

Numerous approaches for treating urinary incontinence are available. One such approach involves the use of a sling. At the present time, however, surgeons using a sling based procedure must grow or harvest autologous tissue or purchase processed cadaveric tissue, animal tissue, or synthetic material from a supplier and fashion the sling during the surgical procedure. Thus, during surgery, the surgeon must cut the sling to the desired dimensions and shape, and attach sutures to the sling. In addition to increasing surgical expense, these steps increase the time required for and complexity of the procedure, thereby increasing surgical morbidity and mortality.

In addition, the slings currently in use are susceptible to tearing at the sites where the sutures are attached to the sling. If the suture attachment sites tear, the sling becomes dislodged and incontinence may result. Additional surgery is required to replace the dislodged sling and restore continence.

Thus, there remains a need for a prefabricated sling which overcomes the above deficiencies. U.S. Patent No. 5,611,515, issued March 18, 1997 to Benderev et al., introduces pioneering minimally invasive percutaneous and transvaginal bladder neck stabilization approaches. The percutaneous approach of Benderev et al. involves stabilizing the bladder neck using a bone anchor which is percutaneously introduced from the abdominal side of the patient. The transvaginal approach of Benderev et al. involves stabilizing the bladder neck using a staple or bone anchor which is transvaginally placed into the pubic bone. The slings of the present invention may be used in several urethral or bladder neck stabilization procedures, including the minimally invasive percutaneous and transvaginal procedures described below and those described in Benderev et al.

Summary of the Invention

The present invention relates to prefabricated urethral stabilization slings, methods of making the slings, methods of attaching sutures to the slings, kits comprising the slings, and methods of using the slings to treat urinary incontinence.

5 One aspect of the invention is a prefabricated sling for improving urinary continence which is made of a biocompatible material and has an elongate shape adapted for urethral stabilization. The biocompatible material has a central portion extending longitudinally between a first end portion and a second end portion and at least a pair of suture receiving sites which comprise a first site located in the first end portion of the material and a second site located in the second end portion of the material. The first site is adapted for receiving at least a first suture and the second site is adapted for receiving at least a second suture. The first site and the second site are generally disposed along a line extending longitudinally relative to the sling.

10 In one embodiment of the sling, the biocompatible material is directionally oriented. For example, the biocompatible directionally oriented material may be longitudinally oriented. In a further embodiment, the first and second end portions of the directionally oriented material have at least one presewn edge and are generally at least twice as thick as the central portion. In yet another embodiment, the first and second suture receiving sites have an inner diameter at least equal to the diameter of the sutures.

15 In a further embodiment of the sling, the biocompatible material is absorbable. In some embodiments of the sling, the biocompatible material is woven.

20 In yet another embodiment of the sling, the biocompatible material is coated. In some embodiments, the coating on the biocompatible material is absorbed after implantation to facilitate tissue ingrowth into the biocompatible material.

In another embodiment of the sling, the biocompatible material is impregnated with an antibiotic. In one embodiment, the sling is impregnated with bacitracin. In another embodiment, the sling is impregnated with polymyxin. In another embodiment the sling is impregnated with neomycin.

25 In some embodiments, the sling is capable of releasing a drug. In further embodiments, the drug is released over time.

The sling may have a visual indicator for indicating the position of the sling relative to the urethra. The visual indicator may comprise at least one transversely extending line in the central portion of the material.

30 In some embodiments, the sling has a stabilizer for further strengthening and further reducing buckling of the sling, the stabilizer being located in the first and second end portions of the sling.

In some embodiments, the material around the periphery of the suture receiving sites is reinforced. In other embodiments, the suture receiving sites are strengthened with a reinforcing device.

35 Another aspect of the present invention is a prefabricated sling for improving urinary continence comprising a biocompatible material having an elongate shape adapted for urethral stabilization. In this aspect of the invention, the biocompatible material has a central portion extending longitudinally between a first end portion and a second end portion. In this aspect of the invention, the sling also has integral attachment members for suspending the sling.

Yet another aspect of the present invention is a kit for performing a urethral stabilization. The kit comprises a sterile biocompatible material having an elongate shape adapted for urethral stabilization. The biocompatible material has a central portion extending longitudinally between a first end portion and a second end portion. The biocompatible material also has at least a pair of suture receiving sites. The pair of suture receiving sites comprises a first suture receiving site located in the first end portion of the biocompatible material and a second suture receiving site located in the second end portion of the biocompatible material. The first suture receiving site is adapted for receiving at least a first suture, and the second suture receiving site is adapted for receiving at least a second suture. The first suture receiving site and the second suture receiving site are generally disposed along a line extending longitudinally relative to the sling.

In one embodiment of the kit, the sling is packaged. In another embodiment of the kit, the first and second suture receiving sites are apertures. In still another embodiment of the kit, the biocompatible material has at least a first and a second suture secured thereto. In a further embodiment of the kit, the biocompatible material is filamentous.

In still another embodiment, the filamentous material is collagen coated. In some embodiments of the kit, the sutures are looped through the apertures.

Yet another aspect of the present invention is a method of making a sling for improving urinary continence. A biocompatible material is cut into an elongate shape adapted for urethral stabilization such that the material has a central portion extending longitudinally between a first end portion and a second end portion. At least a pair of suture receiving sites is formed in the material prior to surgery. The pair of suture receiving sites comprises a first site located in the first end portion of the material and a second site located in the second end portion of the material. The first site is adapted for receiving at least a first suture and the second site is adapted for receiving at least a second suture. The first site and the second site are generally disposed along a line extending longitudinally relative to the sling. In one embodiment, the method further comprises the steps of securing at least a first suture to the first site and securing at least a second suture to the second site. In another embodiment, the method further comprises the step of sterilizing the sling. In yet another embodiment, the method further comprises the step of applying an antibiotic to the sling. In still another embodiment, the method further comprises the step of packaging the sling.

Yet another aspect of the present invention is a method of stabilizing a bladder neck to improve urinary incontinence. In one step of the method, a sling comprising a biocompatible material having an elongate shape adapted for urethral stabilization is provided. The material has a central portion extending longitudinally between a first end portion and a second end portion. The sling also comprises at least a pair of suture receiving sites. In another step of the method, a suture is secured to a bone anchor. In another step of the method, the anchor is positioned in a pubic bone. In yet another step of the method, the suture is secured to at least one of the suture receiving sites in the sling. The suture receiving sites are adapted for receiving at least one suture. The suture receiving sites comprise a first suture receiving site located in the first end portion of the material and a second suture receiving site located in the second end portion of the material. The first suture receiving site is adapted for

receiving at least a first suture and the second suture receiving site is adapted for receiving at least a second suture. The first suture receiving site and the second suture receiving site are generally disposed along a line extending longitudinally relative to the sling. In another step of the method, the bladder neck is stabilized with the sling. In one embodiment, the method further comprises introducing the sling percutaneously. In another embodiment of the method, the sling is introduced without invasive surgery.

Brief Description of the Drawings

Figure 1 is a plan view of a preferred embodiment of the sling of the present invention.

Figure 2A is a plan view of a parallelogram shaped embodiment of the sling of the present invention.

Figure 2B is a plan view of a hexagonal shaped embodiment of the sling of the present invention.

Figure 2C is a plan view of a rectangular shaped embodiment of the sling of the present invention.

Figure 3A is a plan view of a preferred embodiment of the sling of the present invention showing preferred dimensions.

Figure 3B is a cross-sectional view of the sling taken along line 3B-3B of Figure 3A.

Figure 4A is a partial top view of an end portion of a sling having a single suture receiving site.

Figure 4B is a partial top view of a rounded end portion of a sling having two suture receiving sites.

Figure 4C is a partial top view of an end portion of a sling having three suture receiving sites.

Figure 5A is an enlarged top view of an end portion of a sling in which the suture receiving site is an aperture.

Figure 5B is a cross-sectional view of the end portion taken along line 5B-5B of Figure 5A.

Figure 5C is an enlarged top view of an end portion of a sling having a reinforcing device in the suture receiving site.

Figure 5D is a cross-sectional view of the end portion taken along line 5D-5D of Figure 5C.

Figure 5E is an enlarged top view of an end portion of a sling having an alternative reinforcing device in the suture receiving site.

Figure 5F is a cross-sectional view of the end portion taken along line 5F-5F of Figure 5E.

Figure 5G is an enlarged top view of an end portion of a sling having reinforced material around the periphery of the suture receiving site.

Figure 5H is a cross-sectional view of the end portion taken along line 5H-5H of Figure 5G.

Figure 5I is an enlarged top view of an end portion of a sling having reinforced material around an alternative suture receiving site.

Figure 5J is a cross-sectional view of the end portion taken along line 5J-5J of Figure 5I.

Figure 5K is an enlarged top view of an end portion of a sling in which the suture receiving site is an aperture and the material around the periphery of the suture receiving site has been reinforced by heat sealing or ultrasonically sealing.

Figure 5L is a cross-sectional view of the end portion taken along line 5L-5L of Figure 5K.

Figure 6A is a plan view of an unfolded parallelogram shaped piece of biocompatible material.

Figure 6B is a plan view of a hexagonal shaped piece of material obtained by folding the material of Figure 6A as indicated by the arrows in Figure 6A.

Figure 6C is a plan view of a hexagonal shaped sling in which apertures have been formed as suture receiving sites in the end portions of the sling.

5 Figure 6D is a cross-sectional view of the hexagonal shaped sling taken along line 6D-6D of Figure 6C.

Figure 6E is the cross-sectional view of Figure 6D showing sutures secured to the apertures of the sling.

Figure 6F is a plan view of an unfolded rectangular shaped piece of biocompatible material.

Figure 6G is a plan view of a rectangular shaped piece of material obtained by folding the material of Figure 6F as indicated by the arrows in Figure 6F.

10 Figure 6H is a plan view of a rectangular sling in which apertures have been formed as suture receiving sites in the end portions of the sling.

Figure 6I is a cross-sectional view of the rectangular shaped sling taken along line 6I-6I of Figure 6H.

Figure 6J is the cross-sectional view of Figure 6I showing sutures secured to the apertures of the sling.

Figure 6K is a plan view of an unfolded rectangular piece of biocompatible material.

15 Figure 6L is a plan view of a parallelogram shaped piece of material obtained by folding the material of Figure 6K as indicated by the arrows in Figure 6K.

Figure 6M is a plan view of a parallelogram shaped sling in which apertures have been formed as suture receiving sites in the end portions of the sling.

Figure 6N is a cross-sectional view of the parallelogram shaped sling taken along line 6N-6N of Figure 6M.

20 Figure 6O is the cross-sectional view of Figure 6N showing sutures secured to the apertures of the sling.

Figure 7A is a schematic plan view of a parallelogram shaped piece of biocompatible material having longitudinally oriented filaments, grains, striations, or polymeric chains.

Figure 7B is a cross-sectional view of the material taken along line 7B-7B of Figure 7A.

Figure 7C is an enlarged view of the material taken along line 7C-7C of Figure 7A.

25 Figure 7D is an enlarged schematic view of biocompatible material having transversely oriented filaments, grains, striations, or polymeric chains.

Figure 7E is an enlarged schematic view of biocompatible material having diagonally oriented filaments, grains, striations, or polymeric chains.

30 Figure 7F is a schematic plan view of a hexagonal shaped sling obtained by folding the material of Figure 7A as indicated by the arrows in Figure 7A and forming apertures as suture receiving sites in the end portions of the sling.

Figure 7G is an enlarged top view of the sling taken along line 7G-7G of Figure 7F showing the filaments, grains, striations, or polymeric chains in an upper layer of an end portion of the sling crossing the filaments, grains, striations, or polymeric chains in the underlying layer.

35 Figure 8A is an enlarged top view of an end portion of a sling having a suture looped through a plurality of suture receiving sites.

Figure 8B is a cross-sectional view of the sling taken along line 8B-8B of Figure 8A.

Figure 8C is an enlarged top view of an end portion of a sling having a suture threaded through a suture receiving site.

Figure 8D is a cross-sectional view of the sling taken along line 8D-8D of Figure 8C.

5 Figure 8E is an enlarged top view of an end portion of a sling showing a suture looped around the suture receiving site and an edge of the sling.

Figure 8F is a cross-sectional view of the sling taken along line 8F-8F of Figure 8E.

Figure 9A is a plan view of an end portion of a sling having a stabilizer attached thereto.

Figure 9B is a cross-sectional view of the sling taken along line 9B-9B of Figure 9A.

10 Figure 9C is a plan view of an end portion of a sling having a stabilizer between the suture receiving sites.

Figure 9D is a cross-sectional view of the sling taken along line 9D-9D of Figure 9C.

Figure 10A is a plan view of a generally rectangular shaped sling with bilaterally extending integral attachment members.

15 Figure 10B is a plan view of a generally hexagonal shaped sling with bilaterally extending integral attachment members.

Figure 11 is a sagittal section of a female pelvis illustrating the location of the sling of the present invention relative to the bladder neck and the pubic bone.

Figure 12 is a schematic cross-sectional view taken through the urethra and upper vaginal wall illustrating an incision in the upper vaginal wall.

20 Figure 13 is a schematic cross-sectional view taken through the urethra and upper vaginal wall illustrating a bilaterally extending pocket created by blunt dissection.

Figure 14 is a schematic view of a sling of the present invention positioned in the pocket of Figure 13, the sling being suspended from sutures secured to a bone anchor implanted in the pubic bone.

25 Detailed Description of the Preferred Embodiments

The present invention relates to prefabricated slings for use in urethral floor reconstruction. More particularly, the slings are useful for improving or maintaining urinary continence such as by suspending, stabilizing and/or slightly compressing the urethra of an incontinent patient. The slings are particularly useful for treating patients suffering from incontinence caused by Intrinsic Sphincter Deficiency (ISD) and/or hypermobility. The slings may also be used to treat other disorders in which stabilization and/or compression of the urethra would be beneficial.

30 The present slings are designed to be implanted in a patient suffering from incontinence using the medical procedure described in more detail below. During implantation, the sling is preferably positioned beneath the bladder neck so that the urethra extends across the center of the sling. The sling is biased towards the urethra through tension applied to the sling by sutures or other attachment means, which are preferably anchored to the pubic bone. The resulting bias stabilizes and/or slightly compresses the urethra so that continence is maintained.

Although urethral slings have previously been used to treat incontinence, the present slings are prefabricated, eliminating the need for the surgeon to prepare them for use during the surgical procedure. The present slings are supplied to the physician in shapes and dimensions adapted for urethral stabilization or suspension, eliminating the need for the surgeon to cut the sling material during surgery. In addition, the present slings are provided with suture receiving sites already prepared so that the surgeon need not manufacture them during surgery. The slings may also be provided with reinforced suture receiving sites to reduce the incidence of tearing about the point of suture attachment. Because the surgeon need not fabricate the sling during surgery, the time required for the surgical procedure is reduced.

In some embodiments, the slings are provided with the sutures preattached. Alternatively, the slings may have preformed integral attachment members which, like the sutures, allow the sling to be suspended from structures such as the pubic bone. In either case, the need for the surgeon to attach sutures to the sling during surgery is eliminated, thereby simplifying the implantation procedure.

The foregoing features of the present invention overcome the above-discussed deficiencies of slings currently in use. By simplifying and shortening the surgical procedure, use of the slings of the present invention results in decreased surgical morbidity and mortality.

Referring to Figure 1, there is disclosed a plan view of a preferred embodiment of the sling 10 of the present invention. The sling of Figure 1 has been cut into a generally elongate shape adapted for urethral stabilization, with a central portion 12 extending between a first end portion 14 and a second end portion 16. Suture receiving sites 18 are prefabricated in the first and second end portions 14, 16 of the sling 10. The sling preferably also has a visual indicator 20. These and other features of the present invention will be described in more detail below after discussing the materials from which the sling can be constructed.

The sling may be fabricated from any of a variety of synthetic or naturally occurring biocompatible materials. Such materials may be filamentous or non-filamentous, elastic or inelastic, and may be porous, microporous, perforated, or impermeable. The properties of the sling may be selected as appropriate based on the surgical procedure used to implant the sling and the application for which the sling is used.

Filamentous materials suitable for use in the slings of the present invention include cadaveric or animal tissue such as fascia lata, rectus fascia or processed collagen. Synthetic materials such as polyester, polyurethane, or nylon can also be used. The synthetic filamentous material can be woven or non-woven. Filaments made from synthetic materials may be braided together to form strands or threads which can be braided or woven together to form strips of fabric. Preferably, the synthetic filamentous material is polyester.

Non-filamentous materials suitable for use in the slings of the present invention include silicone, polytetrafluoroethylene (PTFE), polyethylene terephthalate (PET), PTFE, FEP, or thin films such as latex.

As will be apparent to one skilled in the art, the elasticity of the sling material may also be selected based on the type of surgical procedure for which the sling is being used. A suitable elastic material is knitted polyester.

As will be apparent to one skilled in the art, inelastic or minimally elastic materials may be preferred for certain procedures such as those in which the sling is used to create an immobile floor. A preferred minimally elastic material is woven polyester.

5 The porosity of the material may also be selected based on the type of surgical procedure for which the sling is being used. For example, pores, micropores, or perforations permit tissue ingrowth, which is advantageous to stabilize the sling and reduce erosion from constant motion.

Additionally, the sling material may be impregnated with antibiotics or other agents which can be delivered from the surface of the sling as well as through the pores, micropores or perforations. Impregnation with antibiotics or other agents may be facilitated by coating the sling with collagen.

10 Impermeable materials may also be useful in certain applications of the sling. Representative impermeable materials include nylons and polyester. A preferred impermeable material is polyester.

A coating may also be applied to the sling. The coating may be used to deliver a number of compounds, such as antibiotics, heparin, immunosuppressant agents or other drugs. In some embodiments, the drug may be released over time. The coating also blocks the interstices of the underlying sling material, thereby decreasing the risk of infection by sequestering the interstices of the sling from contact with microorganisms encountered during implantation of the sling. Preferably, the coating is absorbed after implantation to facilitate tissue ingrowth into the interstices, pores, micropores and/or perforations of the sling material.

20 Suitable coatings include polyglycolic acid, polylactic acid, blends of polyglycolic acid and polylactic acid, gelatin, polyvinyl alcohol, and polyvinyl pyrrolidone. A preferred coating is a smooth layer of collagen, such as that provided on the Hemashield® woven double velour available from Meadox. (Meadox Medical, 112 Beaver Drive, Oakland, NJ 07436 or Boston Scientific Corporation, One Boston Scientific Place, Natick, MA 01760.) The smooth collagen coating protects the interstices of the underlying sling material from bacterial contact during implantation, thereby decreasing the risk of infection as previously discussed. Additionally, the collagen coating facilitates the uptake of antibiotics to reduce the risk of infection as discussed below. After placement in the body, the collagen is gradually absorbed, facilitating tissue ingrowth into the underlying filamentous mesh. The collagen coating may also enhance tissue compatibility.

30 The slings of the present invention may also be made of absorbable materials. Such absorbable slings preferably remain structurally intact for at least three months while supporting tissue ingrowth. Thereafter, the slings may be fully absorbed. Preferably, the slings are fully absorbed over a period of 3-6 months following the three month period in which the sling is intact. Preferably, the absorbable sling is made of polylactic acid or polylactic acid/polyglycolic acid copolymers.

35 The slings of the present invention may be fabricated from directionally oriented biocompatible materials. Such materials include filamentous materials in which the orientation of the filaments is directionally ordered, as well as grained or striated materials in which the grains or striations are directionally ordered. Alternatively, the material may be a polymeric material in which the orientation of the polymeric chains comprising the material is directionally ordered. The polymeric material may or may not be cross-linked.

The filaments, grains, striations, or polymeric chains in such materials may be oriented in a single direction or may be multidirectional. Suitable directionally oriented materials include synthetic materials such as Trelex® Natural Mesh (Meadox Medical, 112 Beaver Drive, Oakland, NJ 07436 or Boston Scientific Corporation, One Boston Scientific Place, Natick, MA 01760.), Hemashield®, and woven and knitted polyester.

Alternatively, the directionally oriented material may be natural material such as grained or striated tissue. The tissue may be an allograft, xenograft, or autologous tissue. One advantage of autologous tissue is its ability to revascularize and regrow after implantation.

Tissue for use in allografts can be obtained from cadavers. Cadaveric tissue can be harvested according to techniques well known to those skilled in the art and may be selected to minimize the risk of rejection. However, non-cadaveric tissue is generally preferred because of patient preference and the perceived risk of cross-contamination. Although the cadaveric tissue may be absorbed after implantation, the scar tissue which replaces the cadaveric tissue provides support for the bladder neck.

Representative sources of autologous tissue for use in the present slings include striated muscle, fascia lata, rectus fascia, dura, pericardium and the vaginal wall. The same tissue sources may also be used for allografts.

Typical sources of xenograft tissue include striated muscle, bovine fascia, dura, pericardium and collagen.

In addition to the synthetic and naturally occurring biocompatible materials enumerated above, those skilled in the art will appreciate that a variety of other materials may be readily employed in the slings of the present invention.

In addition to the elongate octagonal sling illustrated in Figure 1, the slings of the present invention may be cut into a number of other shapes. For example, several alternative elongate shapes suitable for use in the present invention are shown in Figures 2A-2C. These include parallelograms such as rhomboids (Figure 2A), hexagons (Figure 2B), and rectangles (Figure 2C). In addition, the end portion of the sling may be cut into a rounded shape, such as that illustrated in Figure 4B. The optimal shape of the sling is related to anatomical considerations as well as the surgical procedure used to introduce the sling. For instance, slings having rounded ends (Figure 4B) or tapered ends, such as the hexagon (Figure 2B), parallelogram (Figure 2A), and octagon (Figure 1), may facilitate insertion into the pocket formed during the surgical procedure discussed in more detail below, since the pocket may not be precisely rectangular.

The optimal dimensions of the sling can be varied considerably to suit particular design criteria desired for a particular application and still embody the present invention. For example, optimal sling dimensions are dependent upon anatomical considerations and the surgical procedure used to introduce and attach the sling. For instance, the optimal length of the sling may be influenced by whether the surgeon prefers to attach a long strip of material to the pubic bone or abdominal musculature with a bone anchor or other securing device. In such procedures, the sling may be up to 30 cm in length and may be 1-5 cm in width. Preferably, the long slings used in such procedures are 15-30 cm in length and 3-5 cm in width. Shorter slings may be preferred for procedures in which the sling is suspended by a suture bridge. Such slings may be 2.5-7cm in length and 1-5cm in width.

The optimal dimensions of the sling may also be influenced by the sling material selected. For instance, the thickness of the sling material may be dependent on the material selected and the strength and tear resistance required for a particular application of the sling.

The dimensions of the preferred embodiment of Figure 1 are shown in Figures 3A and 3B. The approximate dimensions, in inches, are as follows: A=0.30; B=0.79; C=0.12; D=0.43; F=0.20; G=0.24; H=0.015; I=0.030; and J=0.98. Angle E=22°.

As indicated above, the sling 10 is preferably provided with a visual indicator 20. The visual indicator enables the surgeon to position the sling relative to the urethra so that the urethra generally extends across the center of the sling. In one embodiment, the visual indicator 20 comprises two transversely extending dashed lines in the central portion 12 of the sling 10 as illustrated in Figure 1. However, those skilled in the art will recognize that a variety of other types of visual indicators, including radiopaque indicators, could be used in accordance with the present invention.

The sling of the present invention preferably also has at least one suture receiving site formed in both the first and second end portions of the sling. Preferably, the suture receiving site is an aperture. The aperture may be formed by die stamping the sling material ultrasonic cutting, heat cauterizing, or piercing with a hot poker. Alternatively, the suture receiving site may be sling material as discussed below in regard to Figures 5I and 5J.

The suture receiving site is adapted for receiving at least one suture. Preferably, the suture receiving site has an inner diameter at least equal to the diameter of the suture to be received therein. In the preferred embodiment depicted in Figure 1, both the first and second end portions of the sling have two apertures which are equally displaced from the central longitudinal axis of the sling. However, numerous alternative embodiments are also contemplated by the present invention.

For example, some embodiments of the sling, such as that depicted in Figure 4A, have only one suture receiving site formed per end portion. In such embodiments, the suture receiving site 18 is preferably located along the central longitudinal axis 19 of the sling.

Other embodiments of the sling have 3 or more suture receiving sites formed per end portion. In such embodiments, preferably at least one suture receiving site 18 is located along the central longitudinal axis 19 of the sling with the other suture receiving sites 18 being located symmetrically about the central longitudinal axis 19 as illustrated in Figure 4C.

Preferably, in embodiments in which the number of suture receiving sites in each end portion of the sling is odd, at least one suture receiving site in each end portion of the sling is located along the central longitudinal axis of the sling as shown in Figures 4A and 4C. In those embodiments in which the number of suture receiving sites in each end portion of the sling is even, the suture receiving sites are preferably disposed symmetrically about the central longitudinal axis of the sling as depicted in Figures 1 and 4B.

The use of a plurality of suture receiving sites in each end portion of the sling results in reduced buckling of the sling after implantation compared to embodiments having a single suture receiving site at each end of the sling. Thus, embodiments having a plurality of suture receiving sites in each end portion are preferred.

Although several examples of the locations and number of the suture receiving sites in the end portions of the present slings have been provided above, those skilled in the art will appreciate that additional configurations fall within the scope of the present invention. It will also be appreciated by those skilled in the art that the various configurations and numbers of suture receiving sites described above may be utilized with any of the sling shapes or biocompatible materials described above.

Figure 5 shows various types of suture receiving sites which may be used in the slings of the present invention. In Figures 5A and 5B, the suture receiving site is an aperture formed in the sling material. This type of suture receiving site is employed in the embodiment shown in Figure 1. Preferably, the material around the periphery of the suture receiving sites is reinforced by heat sealing or ultrasonic sealing.

In addition, the suture receiving sites can be strengthened in order to minimize the possibility of tearing. For instance, one piece reinforcing devices may be inserted in the apertures in the sling material. As shown in Figures 5C and 5D, the one piece reinforcing device 22 has an upper rim 24 and a lower rim 26 between which the sling material bordering the suture receiving site is enclosed. Although the upper rim and the lower rim are shown parallel to one another in Figure 5D, alternative embodiments are contemplated in which the upper and lower rims converge towards each other with the sling material therebetween. The upper rim and the lower rim may also be provided with friction enhancing retention structures to minimize the risk of dislodgement of the one piece reinforcing device. Preferably, the one piece reinforcing device 22 is fabricated from biocompatible plastics or metals, such as stainless steel or titanium.

Alternatively, the area around an aperture 18 in the sling material may be strengthened by inserting a multiple piece reinforcing device 28 therein. As illustrated in Figures 5E and 5F, the multiple piece reinforcing device 28 has a first piece 30 and a second piece 32, which interlock and enclose the sling material bordering the suture receiving site. Although the first piece and the second piece are shown parallel to one another in Figure 5F, alternative embodiments are contemplated in which they converge towards each other as discussed above with respect to the one piece reinforcing device. The first piece and the second piece may also be provided with friction enhancing retention structures to minimize the risk of dislodgement of the multiple piece reinforcing device. Preferably, the multiple piece reinforcing device 28 is fabricated from biocompatible plastics or metals, such as stainless steel or titanium.

Yet another way of reducing the risk of tearing comprises reinforcing the sling material around the periphery of the suture receiving sites. Slings having such reinforced material around the periphery of the suture receiving site are depicted schematically in Figures 5G through 5J. In Figures 5G and 5H, the suture receiving site is an aperture. In Figures 5I and 5J, the suture receiving site comprises sling material. In the embodiment of Figures 5I and 5J, the sling material at the suture receiving site provides a puncture target into which the surgeon can insert the suspending suture. In Figures 5K and 5L the suture receiving site is an aperture and the periphery of the suture receiving site is reinforced by heat sealing or ultrasonically sealing. Preferably, the material around the periphery of the suture receiving sites is reinforced by heat sealing or ultrasonic sealing. The reinforced material 34 around the periphery of the suture receiving site shown in Figures 5G through 5L may be formed in a variety of ways, such

as by heat sealing, ultrasonically sealing, or sewing the area of the sling material along the periphery of the suture receiving site.

In further embodiments of the present invention, the periphery of the suture receiving sites is strengthened by making the end portions of the sling thicker than the central portion as shown in Figures 6A-6O. One way to fabricate slings in which the end portions are thicker than the central portion is to fold the end portions of the sling. For example, a hexagonal shaped piece of material, shown in Figure 6B, may be formed by folding the parallelogram shaped piece of biocompatible material shown in Figure 6A along the lines indicated in Figure 6A. Alternatively, the hexagonal material of Figure 6B may be formed by folding a trapezoidal piece of material, as will be apparent to one skilled in the art. Suture receiving sites may be formed in the hexagonal shaped intermediate of Figure 6B to form the hexagonal shaped sling of Figure 6C, in which the end portions 14, 16 are generally twice the thickness of the central portion 12 of the sling. A cross-sectional view of the hexagonal shaped sling depicting the double thickness end portions is shown in Figure 6D. Figure 6E illustrates a suture 36 secured in the suture receiving site 18. The suture can be secured to the suture receiving site during the manufacturing process of the sling or by the physician prior to or during surgery.

In another embodiment, a rectangular piece of material, shown in Figure 6G, may be formed by folding the rectangular piece of biocompatible material shown in Figure 6F along the lines indicated in Figure 6F. Suture receiving sites may be formed in the rectangular shaped intermediate of Figure 6G to form the rectangular sling of Figure 6H, in which the end portions 14, 16 are generally twice the thickness of the central portion 12 of the sling. A cross-sectional view of the rectangular shaped sling depicting the double thickness end portions is shown in Figure 6I. Figure 6J illustrates a suture 36 secured in the suture receiving site 18 as discussed above with regard to Figure 6E.

In a further embodiment, a rhomboid shaped piece of material, shown in Figure 6L, may be formed by folding the rectangular piece of biocompatible material shown in Figure 6K along the lines indicated in Figure 6K. Suture receiving sites may be formed in the rhomboid shaped intermediate of Figure 6L to form the rhomboid shaped sling of Figure 6M, in which the end portions 14, 16 are generally twice the thickness of the central portion 12 of the sling. A cross-sectional view of the rhomboid shaped sling depicting the double thickness end portions is shown in Figure 6N. Figure 6O illustrates a suture 36 secured in the suture receiving site 18 as discussed above with regard to Figures 6E and 6J.

Those skilled in the art will appreciate that slings in which the end portions are thicker than the central portion may be made in any of the shapes and configurations disclosed herein and are not limited to the shapes illustrated in Figures 6A-6O.

In some embodiments of the present invention, at least one edge 38, 40, 42 or 44 of each double thickness end portion 14, 16 is secured to an adjacent layer of the sling either during manufacturing of the sling or by the physician prior to or during the surgical procedure. Alternatively, the sling may be supplied to the surgeon with at least one edge 38, 40, 42 or 44 of each double thickness end portion 14, 16 already secured. Preferably, the edge 38 closest to the central portion 12 is sewn. More preferably, all edges 38, 40, 42 and 44 are secured. In those

embodiments in which the sling is made from natural tissue, the edge 42 where the fold was made is preferably not secured, although the other edges 38, 40 and/or 44 of the double thickness end portions may be secured. Numerous methods familiar to those skilled in the art may be used to secure the edges, such as sewing, heat sealing, ultrasonic sealing, stapling or gluing. Preferably, the edges are secured by sewing during the manufacturing process or prior to surgery, and by sewing, stapling or gluing during the surgical procedure.

As will be apparent to one of skill in the art, slings having end portions that are thicker than the central portion can be made in a variety of ways other than those described above. For example, the sling material may be folded over on itself more than once to produce slings with end portions more than twice as thick as the central portion. Alternatively, an additional layer or layers of separately cut material could be secured to the end portions of the sling, thereby producing a sling having end portions of varying thickness. Slings having two or more layers of material in both the end portions and the central portion are also contemplated. Such slings can be formed by securing the upper layer or layers of sling material to the lower layer or layers using the methods discussed above.

In addition to the resistance to tearing provided by slings in which the suture receiving sites are located in end portions that are thicker than the central portion, a further benefit is provided by securing the upper layer of the vertical edge 38 to the lower layer of the sling. In particular, the secured vertical edge 38 acts as a reinforcing rib which reduces buckling of the sling when the sling is placed under tension after implantation in the patient.

If the suture receiving sites are strengthened using the one piece reinforcement devices, two piece reinforcement devices, or reinforced material around their periphery as described above, the edges 40, 42, 44 of the double thickness end portions of the sling may be secured. The vertical edge 38, however, may be secured to reduce buckling as described above.

Yet a further advantage is provided by forming end portions having double thickness in slings made of directionally oriented materials such as the materials shown in Figures 7A-7G. The directionally ordered filaments, grains, striations or polymeric chains may be oriented in a variety of directions. For example, Figures 7C-7E illustrate enlarged views of sling materials having longitudinally (Fig. 7C), transversely (Fig. 7D), and diagonally (Fig. 7E) oriented filaments, grains, striations or polymeric chains 46, all of which are suitable for use in the present invention. Figure 7B is a schematic view of grained materials suitable for use with the present invention. Those skilled in the art will appreciate that the grained materials may have ridges or grooves therein, or may have a smooth surface. Materials having multidirectional filaments, grains, striations or polymeric chains are also suitable for use in the present invention.

The parallelogram or rhomboid shaped material of Figure 7A can be folded along the indicated lines to form the hexagonal shaped sling having double thickness end portions shown in Figure 7F as described above with regard to Figures 6A-6E. As can be seen in Figures 7F and 7G, when the directionally oriented material is folded over on itself, the filaments, grains, striations or polymeric chains in the upper layer of the double thickness end portion cross the filaments, grains, striations or polymeric chains in the lower layer of the end portion. This nonparallel orientation of the layers of the material relative to each other provides additional protection against tearing in the regions of

the sling surrounding the suture receiving sites by having the strength of the grain perpendicular to the suture pull direction.

Slings having two or more layers of directionally oriented material in both the end portions and the central portion, wherein the filaments, grains, striations or polymeric chains in the different layers cross are also contemplated.

In another embodiment, the slings may have a stabilizer attached to the end portions 14, 16 to reduce buckling of the sling 10 and to provide additional strength to the sling 10, as depicted in Figures 9A-9D. Preferably, the stabilizer is made of metal or plastic. The stabilizer may be attached to the sling in a variety of manners such as sewing, heat sealing, mechanical securement, or capturing the stabilizer between a fold in the sling material. In some embodiments, the stabilizer may also be provided with friction enhancing retention structures to minimize the risk of dislodgement of the stabilizer.

In one embodiment, the stabilizer may be attached to an edge at each end of the sling as illustrated in Figures 9A and 9B. The stabilizer may comprise a first side 68, a second side 70, and an intermediate section 72 disposed between the first side 68 and the second side 70. In this embodiment, the stabilizer preferably contacts both sides of the sling 10.

In an alternate embodiment, the stabilizer may comprise a single section 73 which is disposed between the suture receiving sites 18 and is attached to one side of the sling as illustrated in Figures 9C and 9D.

Those skilled in the art will appreciate that additional stabilizer designs and locations are possible. For example, a stabilizer which is located at each end of the sling may contact a single side of the sling 10. In other embodiments, the sling may have one or more stabilizers in the central portion 12 in addition to the stabilizers in the end portions 14, 16. In addition, those skilled in the art will appreciate that the stabilizers may be used in conjunction with any of the sling embodiments described herein.

As previously discussed, the slings can be supplied to the surgeon with the sutures preattached or the sutures can be attached to the suture receiving sites by the surgeon. In either case, a variety of suture attachment methods are contemplated by the present invention.

For example, Figure 8A shows an enlarged top view of an end portion of a sling having two suture receiving sites 18 with a suture 36 secured thereto. In this embodiment, the suture 36 is looped through the suture receiving sites 18, as illustrated in the cross-sectional view of Figure 8B. Alternatively, the suture can be threaded through one suture receiving site and out the other suture receiving site without looping through the sling material therebetween.

Alternatively, the suture 36 can be threaded through a single suture receiving site 18 as illustrated in Figures 8C and 8D.

Another method of attaching the suture to the sling is illustrated in Figures 8E and 8F. In accordance with this method, the suture 36 is looped around the suture receiving site 18 and the edge of the sling.

While Figures 8A-8F show a variety of methods for attaching the suture to the sling, those skilled in the art will appreciate that other methods may also be used.

Yet another method of attaching the suture 36 utilizes a connector to link the suture to the sling. Suitable connectors for linking the suture to the sling are disclosed in the copending U.S. Patent Application entitled "Method and Apparatus for Minimally Invasive Pelvic Surgery," (VESITEC.028A), filed February 13, 1998 and the identically titled U.S. Provisional Patent Application Serial No. 60/038,380 filed February 13, 1997. In such embodiments, the sling has a ring member therein to permit the connector to be attached to the sling. Ring members suitable for attaching the connector are also disclosed in the copending U.S. Patent Application entitled "Method and Apparatus for Minimally Invasive Pelvic Surgery," filed simultaneously herewith and the identically titled U.S. Provisional Patent Application Serial No. 60/038,380 filed February 13, 1997.

Those skilled in the art will appreciate that a variety of other suture attachment methods can be used in accordance with the present invention.

The present invention also includes prefabricated slings having integral attachment members 148. Such slings can be die cut or ultrasonically cut out of a solid sheet of biocompatible material. Preferably, the slings having integral attachment members are cut from one length of material and the edges are heat sealed. Alternatively, the integral attachment members may comprise trailing filaments such as longer strands in a woven sling. In a further embodiment, the integral attachment members comprise filaments interwoven through the sling material. The function of the integral attachment members 148 is similar to that of the sutures 36, which allow the surgeon to suspend the sling from a structure, such as the pubic bone as described in more detail below.

Representative examples of slings having integral attachment members are depicted in Figures 10A and 10B. Figure 10A shows a generally rectangular shaped sling 110 in which bilaterally extending integral attachment members 148 are formed from the same piece of material as the sling. Figure 10B shows a generally hexagonal shaped sling 110 in which bilaterally extending integral attachment members 148 are formed from the same piece of material as the sling. Those skilled in the art will appreciate that slings with integral attachment members having configurations other than those shown in Figures 10A and 10B are also contemplated by the present invention.

The slings of the present invention may be individually packaged and/or sterilized prior to purchase. The packaging may protect the sling during storage. For example, in embodiments in which the sling material comprises a collagen coated filamentous material, the packaging may protect the sling from damage by ultraviolet light. The sling may be soaked in an antibiotic solution, such as a solution of neomycin, bacitracin, or polymyxin, to prevent microorganisms from collecting on and colonizing the surface of the sling during manipulation, thereby reducing the risk of infection following implantation of the sling. The sling may also be sterilized by ethylene oxide or irradiation. Uptake and delivery of the antibiotic may be enhanced by using a coated sling as described above.

In embodiments in which the sling is made of natural tissue, the sling may be stored in glutaraldehyde or freeze dried. Prior to use in the surgical procedure, the natural tissue may be preconditioned by soaking the sling in a saline solution, such as any standard commercially available saline solution.

The present invention also includes a stabilization sling kit for maintaining urinary continence. Preferably, the kit comprises a prepackaged sling. More preferably, the kit comprises a sterilized sling. In one embodiment, the

kit includes a sling having sutures secured thereto. Alternatively, the sling included in the kit may have integral attachment members as described above.

A minimally invasive percutaneous method of sling delivery and stabilization to treat an incontinent patient will now be described with reference to Figures 11 - 14. Preoperatively, the patient receives broad spectrum antibiotics, such as gentamicin and ampicillin. The patient is placed in the dorsal lithotomy position and regional or general anesthesia is administered. Preparation of the patient emphasizes isolation of the anus with a stapled towel or plastic drape. A Foley catheter is placed.

An approximately 1-2 centimeter midline incision 52 is made in the upper vaginal wall 54 beneath the bladderneck, such as at the urethro-vesical junction, as illustrated in Figure 12. The surgeon then inserts an instrument such as surgical scissors through the incision in the upper vaginal wall and bluntly dissects the tissue on both sides of the urethra 56 to create a bilaterally extending pocket 60, which is illustrated in Figure 13.

The bilaterally extending pocket can also be created and the sling can be inserted using a variety of other minimally invasive instruments/methods including the transvaginal, hiatal and percutaneous approaches disclosed in the copending U.S. Patent Application entitled "Transvaginal Anchor Implantation Device," Serial No. 08/744439 filed November 8, 1996, the copending U.S. Patent Application entitled "Percutaneous and Hiatal Devices and Methods for Use in Minimally Invasive Pelvic Surgery" (VESITEC.029A), filed February 13, 1998, the identically titled U.S. Provisional Patent Application Serial No. 60/038,171, filed February 13, 1997, the copending U.S. Patent Application entitled "Method and Apparatus for Minimally Invasive Pelvic Surgery" (VESITEC.028A), filed February 13, 1998, and the identically titled U.S. Provisional Patent Application Serial No. 60/038,380, filed February 13, 1997.

For example, these other approaches may be employed when the physician desires to attach a long strip of material to the pubic bone or other structures such as the abdominal musculature with a bone anchor or other securing device. In such approaches, an opening capable of accommodating the long strip of material is created in the body tissue, the sling is introduced into the opening in the body tissue, and the sling is attached directly or indirectly to the pubic bone or other structures such as the abdominal musculature.

Either before or after creating the pocket 60, a bone anchor 62, such as a screw in anchor, a push in anchor, or a punch in anchor, is introduced into the pubic bone 64 for fixation of suspensory sutures, with or without pre-drilling a hole in the pubic bone. For instance, the bone anchor is introduced using a bone anchor implantation device of a type such as that illustrated in Figures 15-19 of copending U.S. Application Serial No. 08/385,897, filed February 9, 1995. Bone anchor sites are located by placing the bone anchor implantation device on the body over the area of the pubic bone after visualization or digital palpation over the bone. The surgeon then extends the bone probes distally until both probes have made contact with the pubic bone. Preferably, one anchor 62 for each side (two per patient) is implanted into the tubercle portions of the pubic bone 64 (approximately two centimeters lateral to the symphysis pubis). Preferably, the eyelet of the anchor is recessed below the surface of the bone or flush with the surface of the bone. The anchor 62 preferably has a suture 36 slidably secured thereto prior to

implantation of the anchor into the pubic bone so that a first suture end and a second suture end extend from the implanted anchor after removal of the anchor driver.

Two separated approximately one inch transverse incisions are made over the pubic bone as illustrated in the U.S. Patent No. 5,611,515, issued March 18, 1997 to Benderev et al., and dissection is carried down to the area of the rectus fascia. The first end of the anchored suture is manually placed into a suture channel of a suture passer of a type such as that illustrated in Figures 45 and 45a of the above incorporated U.S. Patent No. 5,611,515, issued March 18, 1997 to Benderev et al. The probe is moved distally to lock the suture therein.

Beginning on the right side, the suprapubic wound is stretched cephalad to allow the vertical passage of the suture passer through the rectus fascia with the probe tip fully exposed. Distal advancement of the suture passer is accomplished with the tip proximally retracted within the probe guide. The suture passer is acutely angled into the abdomen so that the point rests on the underside of the pubic periosteum.

While maintaining contact with the underside of the pubis, the suture passer with the probe tip retracted is thereafter passed distally toward the introitus. At the completion of this distal passage, the suture passer can be palpated through the introitus to the right of the urethra 56. The distal end tip of the suture passer is withdrawn from the surface of the pubourethral ligament and gently swept along the pubocervical fascia to the area of the bladder neck under the guidance of a finger within the vagina. Palpation through the vagina may be safely performed to assist in localization of the suture passer tip.

The probe tip is then distally extended. The suture passer is then passed through the endopelvic fascia and into the pocket 60 between the urethra 56 and the upper vaginal wall 54 at which time the probe tip is retracted. The surgeon then guides the suture passer distally into the vagina through the midline incision 52 in the upper vaginal wall 54. The probe is then retracted maximally to the unlocked position to allow the first end of the suture to be manually removed from the suture channel.

The surgeon selects a sling, such as sling 10 of the present invention. The surgeon secures the suture 36 to a first end portion 14 of the sling by advancing the first end of the suture through the suture receiving site 18 as previously described.

After securing the suture 36 to the first end portion of the sling 10, the first end of the suture is placed into the unlocked suture channel and locked into place. The suture passer and suture locked therein are then pulled up through the suprapubic wound. The first end of the suture is then released from the suture channel by manually retracting the probe.

The identical procedure is performed on the left side.

The surgeon places the sling 10 into the pocket 60 through the midline incision 52 in the upper vaginal wall 54. The sling is placed under the urethra, preferably under the bladderneck, in order to realign the urethra and bladderneck to the correct anatomical position and provide a stable floor to counteract internal stresses.

As will be apparent to one of skill in the art, the sling may be placed beneath the bladderneck in a variety of ways other than via the pocket 60. For instance, an inverted U shaped incision may alternatively be made

beneath the bladderneck. The tissue beneath the inverted U shaped incision may be bluntly dissected to create a flap. The sling may then be inserted in the dissected opening.

After placing the sling in the pocket or opening, the surgeon aligns the sling so that the visual indicator 20 is located directly beneath the urethra 56. As will be apparent to one of skill in the art, alignment of the sling relative to the urethra can be accomplished in a variety of ways, such as by direct visualization.

After the sling 10 is correctly positioned, the first and second ends of the suture on each side are tied to each other with sufficient tension to stabilize and support the bladder neck as illustrated in Figures 11 and 14. The Foley catheter is removed prior to tying the suspensory sutures.

In order to minimize postoperative urinary blockage caused by excessive tension, and minimize postoperative urinary incontinence due to insufficient tension, suture tension is regulated by tying the first and second ends of the sutures across a suture tensioner of a type such as that illustrated in Figures 46-49 of the above incorporated U.S. Patent No. 5,611,515, issued March 18, 1997 to Benderev et al. The suture tensioner is thereafter removed and the position of the visual indicator 20 relative to the urethra is reconfirmed prior to closing the vaginal and suprapubic wounds.

The wounds are irrigated with an antibiotic solution, such as a bacitracin solution. The wound edges and the rectus fascia at the suture entry points are infiltrated with bupivacaine. A Foley catheter is introduced. Alternatively, a suprapubic tube can be placed, especially in those patients having dexterity problems or an aversion to learning intermittent catheterization.

Following surgery, the patient is given either ciprofloxacin or ofloxacin for ten days. For those patients having a Foley catheter, the catheter is removed approximately one week following surgery. The patient performs intermittent catheterization as necessary until the post-void residuals are less than 75 cc on two consecutive catheterizations. In patients having a suprapubic tube, the suprapubic tube is removed when the post-void residuals are less than 75 cc following two consecutive urinations.

As will be apparent to one of skill in the art, the foregoing method can be readily modified for use with sling 110 in which the function of the integral attachment members 148 is similar to that of the sutures 36 described above. In addition, while the foregoing procedure was described using two bone anchors per patient, one of ordinary skill in the art will recognize that the procedure could also be accomplished using either one anchor per patient or greater than two anchors per patient. The one anchor embodiment is especially preferred for use with slings having a single suture end or single integral attachment member extending from each end of the sling, such as the sling 110 illustrated in Figure 10B. In those cases where one anchor per patient is used, the anchor is preferably located adjacent to the symphysis pubis. The slings of the present invention can also be suspended from structures other than bone, such as Cooper's ligament or the rectus fascia without using bone anchors.

Although this invention has been described in terms of certain preferred embodiments, other embodiments which will be apparent to those of ordinary skill in the art in view of the disclosure herein are also within the scope of this invention. Accordingly, the scope of the invention is intended to be defined only by reference to the appended claims.

WHAT IS CLAIMED IS:

1. A prefabricated sling for improving urinary continence, said sling comprising:
a biocompatible material having an elongate shape adapted for urethral stabilization, said material having a central portion extending longitudinally between a first end portion and a second end portion; and
5 at least a pair of suture receiving sites, said pair of suture receiving sites comprising a first site located in said first end portion of said material and a second site located in said second end portion of said material, said first site being adapted for receiving at least a first suture and said second site being adapted for receiving at least a second suture, said first site and said second site being generally disposed along a line extending longitudinally relative to said sling.
- 10 2. The sling of Claim 1, wherein said biocompatible material is directionally oriented.
3. The sling of Claim 2, wherein said directionally oriented biocompatible material is longitudinally oriented.
4. The sling of Claim 2, wherein said first and second end portions of said directionally oriented material have at least one presewn edge and are generally at least twice as thick as said central portion.
- 15 5. The sling of Claim 4, wherein said first and second suture receiving sites have an inner diameter at least equal to the diameter of said sutures.
6. The sling of Claim 1, wherein said biocompatible material is absorbable.
7. The sling of Claim 1, wherein said biocompatible material is woven.
8. The sling of Claim 1, wherein said biocompatible material is coated.
- 20 9. The sling of Claim 8, wherein the coating on said biocompatible material is absorbed after implantation to facilitate tissue ingrowth into said biocompatible material.
10. The sling of Claim 1, wherein said biocompatible material is impregnated with an antibiotic.
11. The sling of Claim 10, wherein said antibiotic is bacitracin.
12. The sling of Claim 10, wherein said antibiotic is polymyxin.
- 25 13. The sling of Claim 10, wherein said antibiotic is neomycin.
14. The sling of Claim 1, wherein said sling is capable of releasing a drug.
15. The sling of Claim 14, wherein said drug is released over time.
16. The sling of Claim 1, further comprising a visual indicator for indicating the position of said sling relative to the urethra.
- 30 17. The sling of Claim 16, wherein said visual indicator comprises at least one transversely extending line in the central portion of said material.
18. The sling of Claim 1 further comprising a stabilizer for further strengthening and further reducing buckling of said sling, said stabilizer being located in said first and second end portions of said sling.
19. The sling of Claim 1, wherein the material around the periphery of said suture receiving sites is
35 reinforced.
20. The sling of Claim 1, wherein said suture receiving sites are strengthened with a reinforcing device.

21. A prefabricated sling for improving urinary continence, said sling comprising:
a biocompatible material having an elongate shape adapted for urethral stabilization, said material having a central portion extending longitudinally between a first end portion and a second end portion; and integral attachment members for suspending said sling.
- 5 22. A kit for performing a urethral stabilization, said kit comprising:
a sterile biocompatible material having an elongate shape adapted for urethral stabilization, said biocompatible material having a central portion extending longitudinally between a first end portion and a second end portion; and
at least a pair of suture receiving sites, said pair of suture receiving sites comprising a first suture receiving site located in said first end portion of said biocompatible material and a second suture receiving site located in said second end portion of said biocompatible material, said first suture receiving site being adapted for receiving at least a first suture, and said second suture receiving site being adapted for receiving at least a second suture, said first suture receiving site and said second suture receiving site being generally disposed along a line extending longitudinally relative to said sling.
- 10 23. The kit of Claim 22, wherein said sling is packaged.
- 15 24. The kit of Claim 23, wherein said first and second suture receiving sites are apertures.
25. The kit of Claim 24, wherein said biocompatible material has at least a first and a second suture secured thereto.
- 20 26. The kit of Claim 25, wherein said biocompatible material is filamentous.
27. The kit of Claim 26, wherein said filamentous material is collagen coated.
28. The kit of Claim 27, wherein said sutures are looped through said apertures.
29. A method of making a sling for improving urinary continence, comprising:
cutting a biocompatible material into an elongate shape adapted for urethral stabilization such that said material has a central portion extending longitudinally between a first end portion and a second end portion; and
forming at least a pair of suture receiving sites in said material prior to surgery, said pair of suture receiving sites comprising a first site located in said first end portion of said material and a second site located in said second end portion of said material, said first site being adapted for receiving at least a first suture and said second site being adapted for receiving at least a second suture, said first site and said second site being generally disposed along a line extending longitudinally relative to said sling.
- 25 30. The method of Claim 29, further comprising the steps of securing at least a first suture to said first site and securing at least a second suture to said second site.
- 30 31. The method of Claim 29, further comprising the step of sterilizing said sling.
32. The method of Claim 29, further comprising the step of applying an antibiotic to said sling.
- 35 33. The method of Claim 29, further comprising the step of packaging said sling.
34. A method of stabilizing a bladder neck to improve urinary incontinence comprising the steps of:

providing a sling comprising a biocompatible material having an elongate shape adapted for urethral stabilization, said material having a central portion extending longitudinally between a first end portion and a second end portion, said sling also comprising at least a pair of suture receiving sites;

securing a suture to a bone anchor;

5 positioning said anchor in a pubic bone;

securing said suture to at least one of said suture receiving sites in said sling, said suture receiving sites being adapted for receiving at least one suture, said suture receiving sites comprising a first suture receiving site located in said first end portion of said material and a second suture receiving site located in said second end portion of said material, said first suture receiving site being adapted for receiving at least a first suture and said second suture receiving site being adapted for receiving at least a second suture, said first suture receiving site and said

10

stabilizing said bladder neck with said sling.

35. The method of Claim 34, further comprising introducing said sling percutaneously.

36. The method of Claim 34, wherein said sling is introduced without invasive surgery.

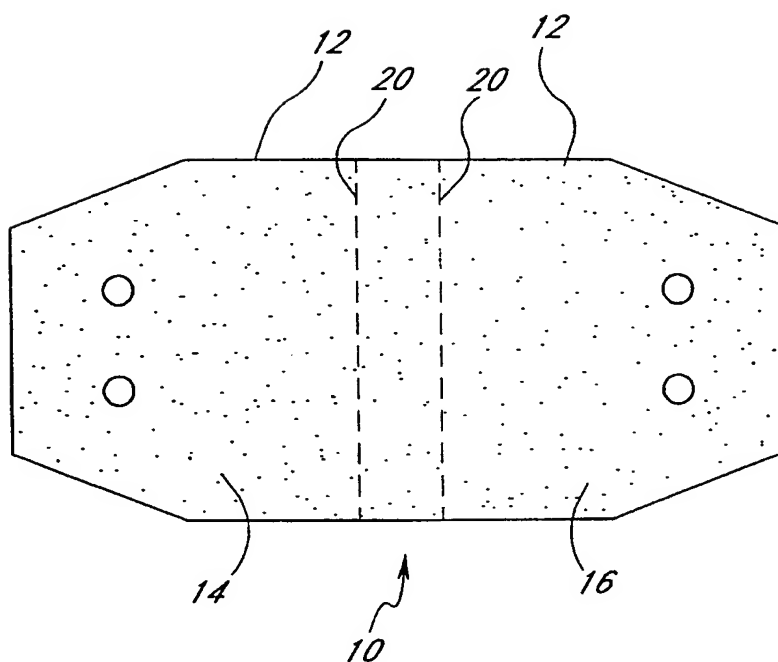
Fig. 1

Fig. 2A

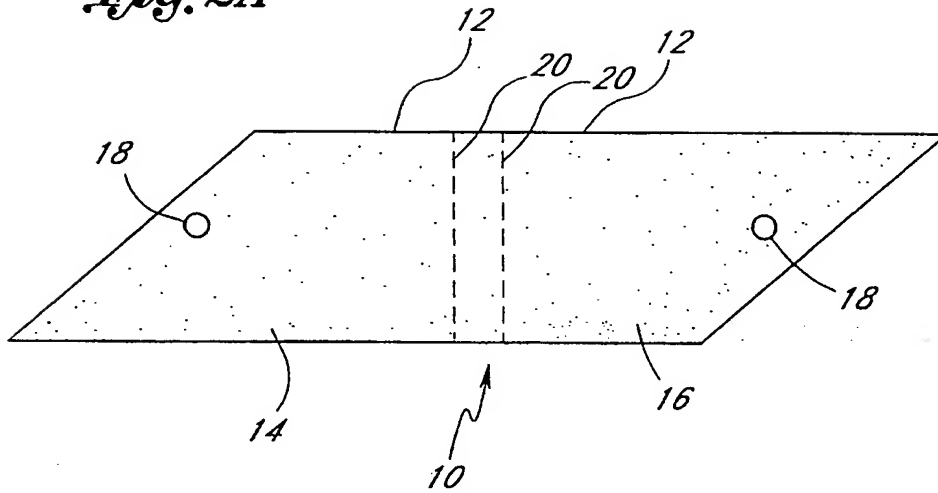


Fig. 2B

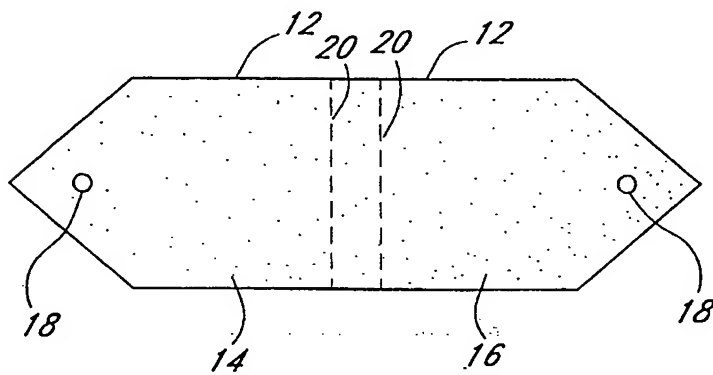
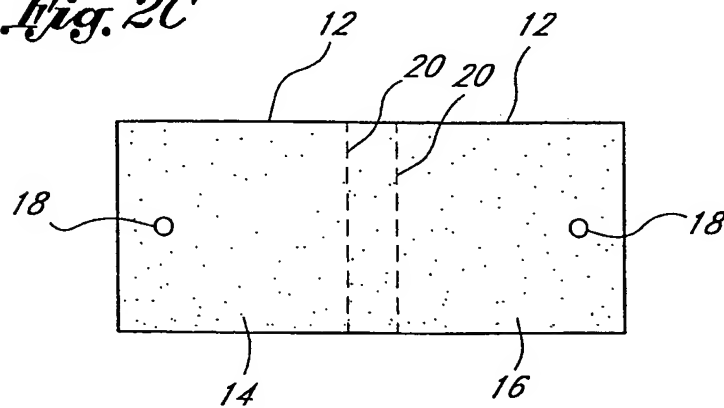


Fig. 2C



3/17⁴

Fig. 3A

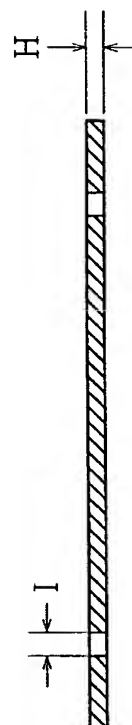
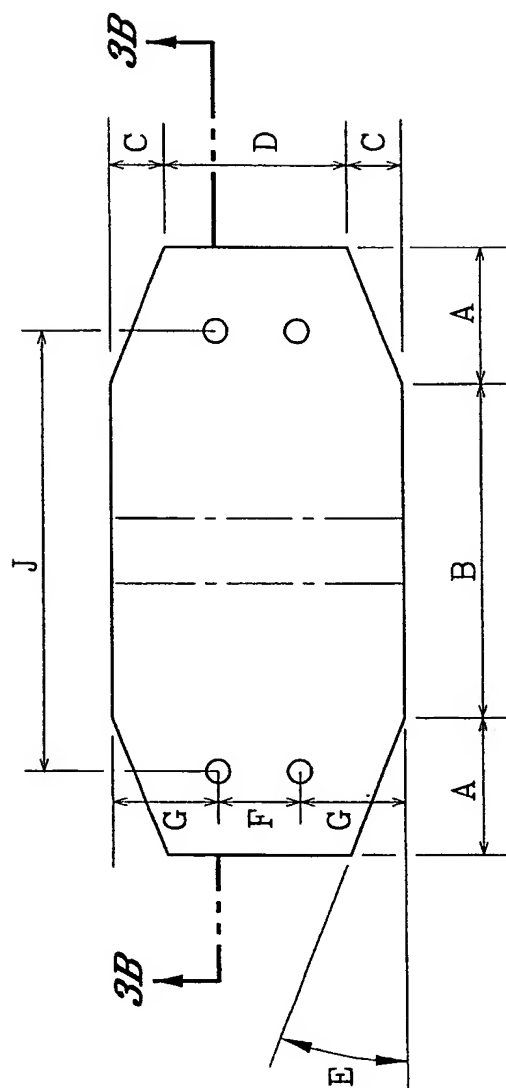


Fig. 3B

4/17

Fig. 4A

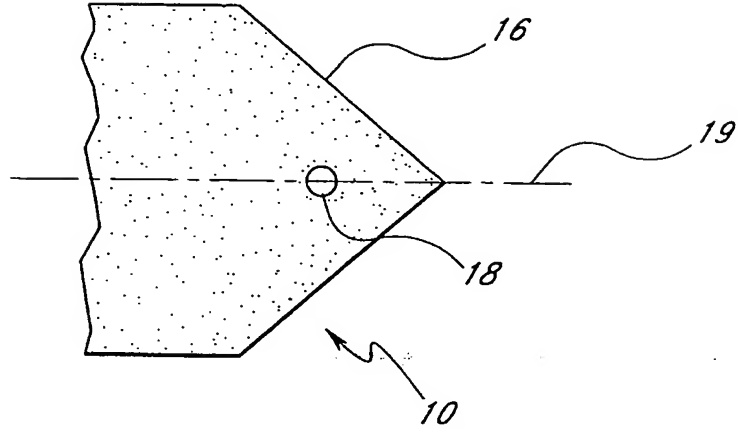


Fig. 4B

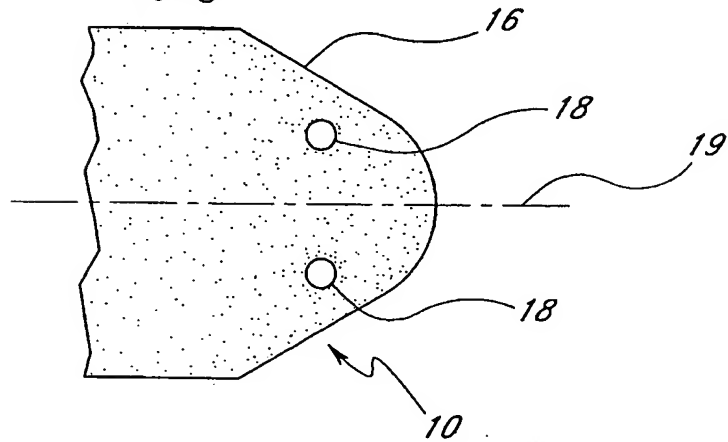
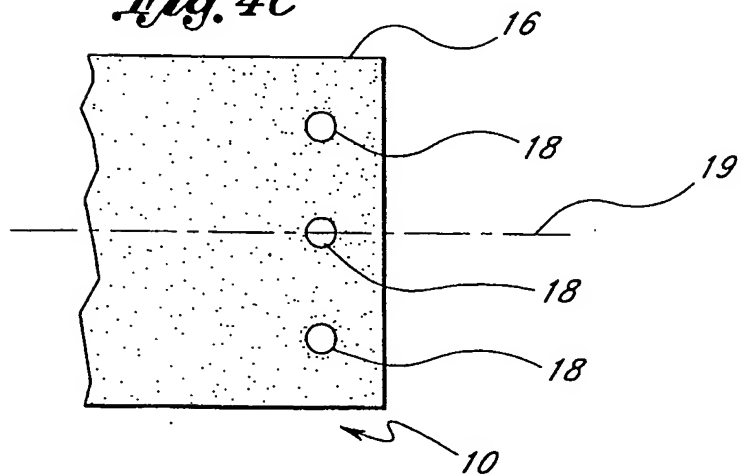


Fig. 4C



5/17

Fig. 5A

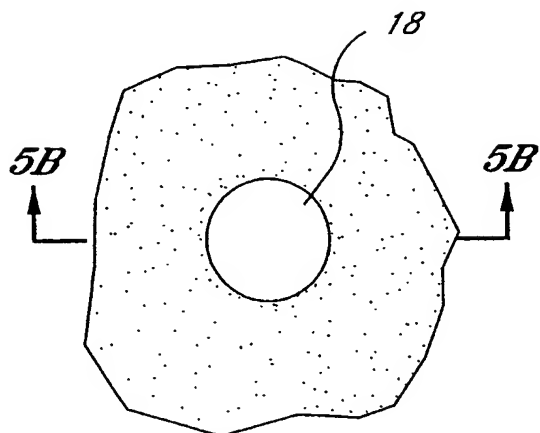


Fig. 5C

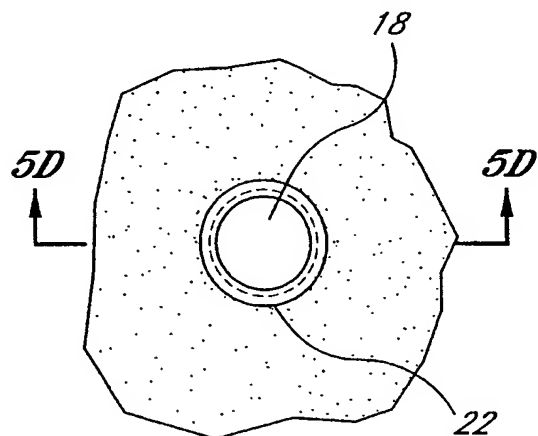


Fig. 5B

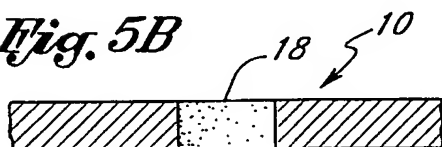


Fig. 5D

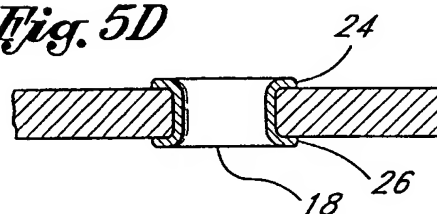


Fig. 5E

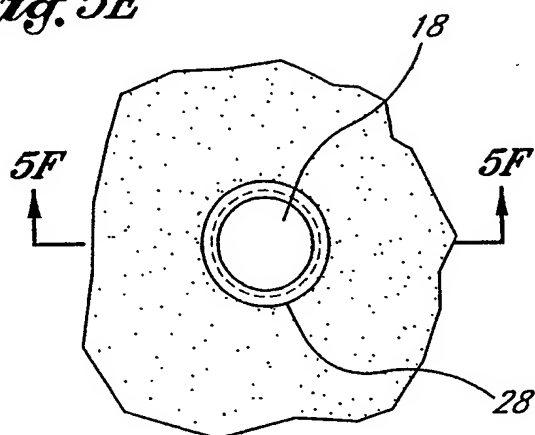
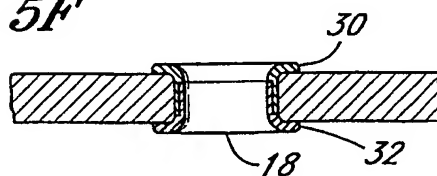


Fig. 5F



6/17

Fig. 5G

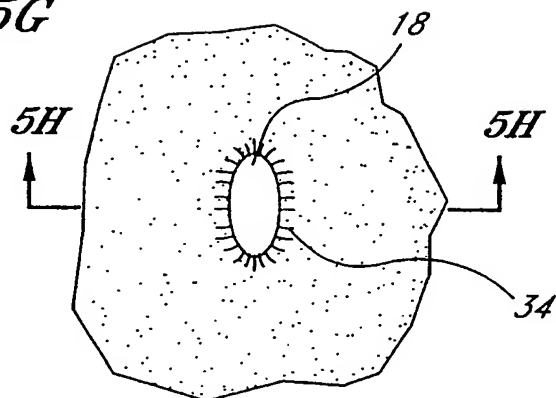


Fig. 5H

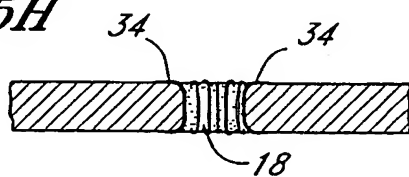


Fig. 5I

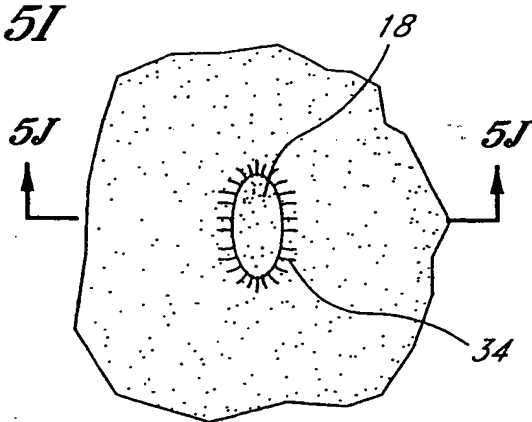
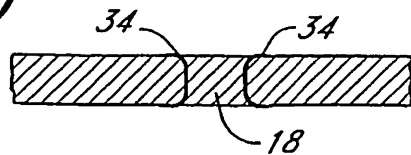


Fig. 5J



7/17

Fig. 5K

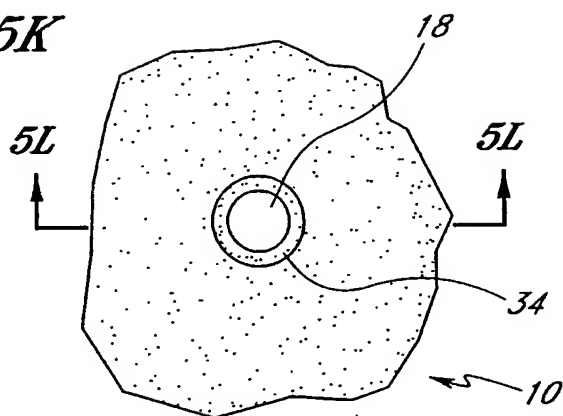
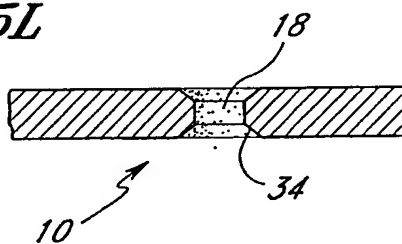


Fig. 5L



8/17

Fig. 6A

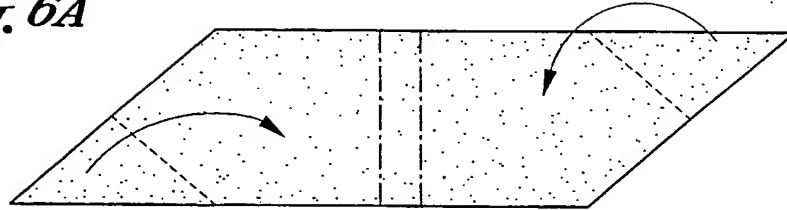


Fig. 6B

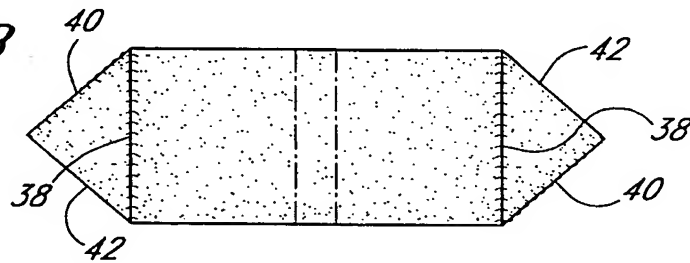


Fig. 6C

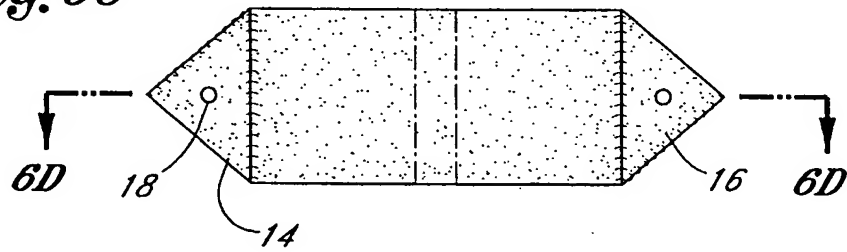


Fig. 6D

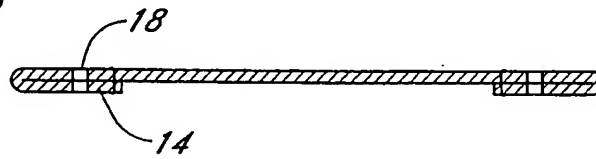


Fig. 6E

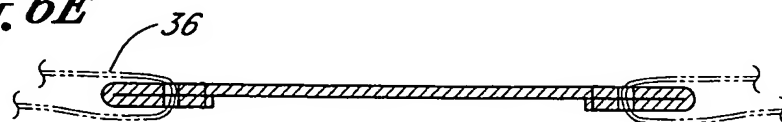


Fig. 6F

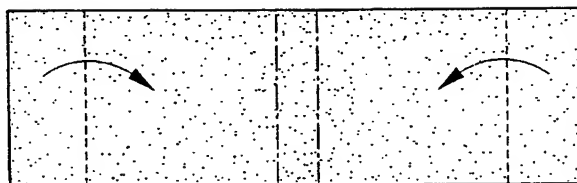


Fig. 6G

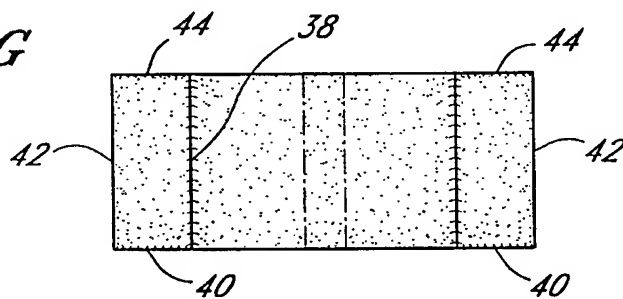


Fig. 6H

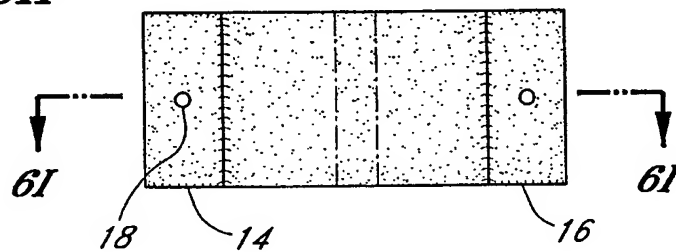


Fig. 6I

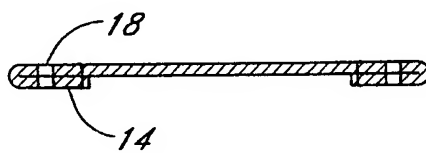


Fig. 6J

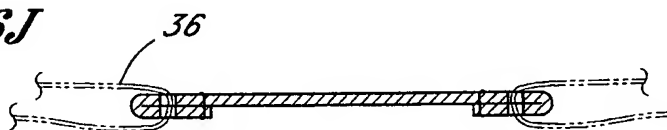


Fig. 6K

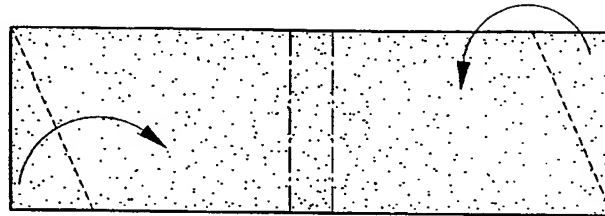


Fig. 6L

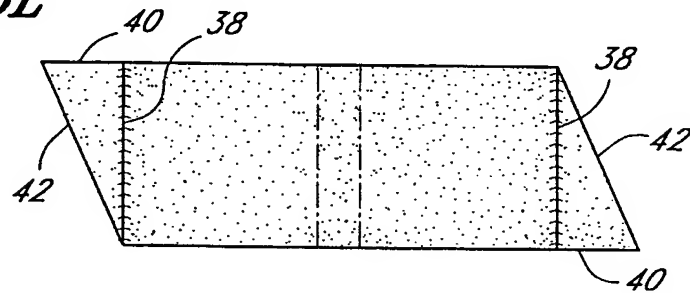


Fig. 6M

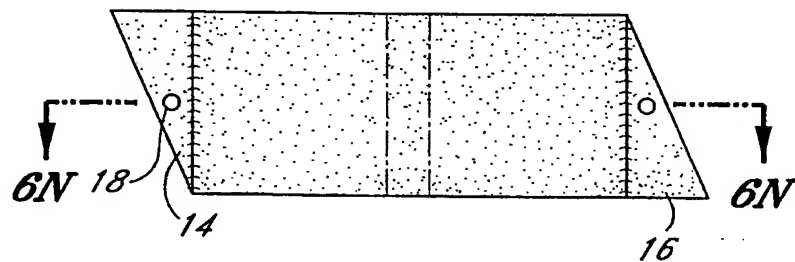


Fig. 6N

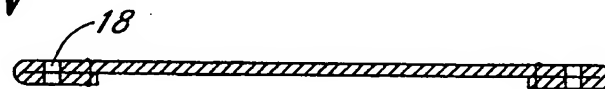
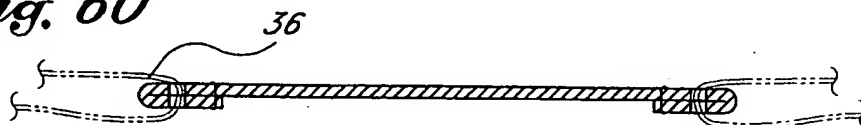


Fig. 6O



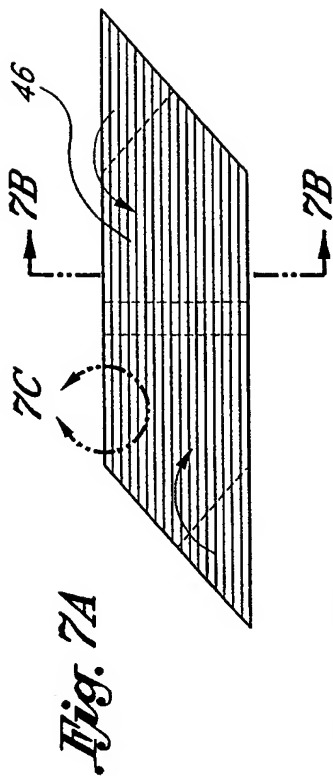


Fig. 7B

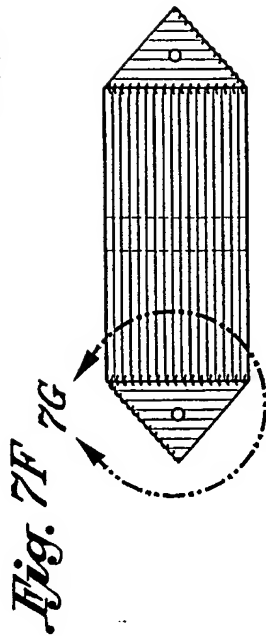


Fig. 7C

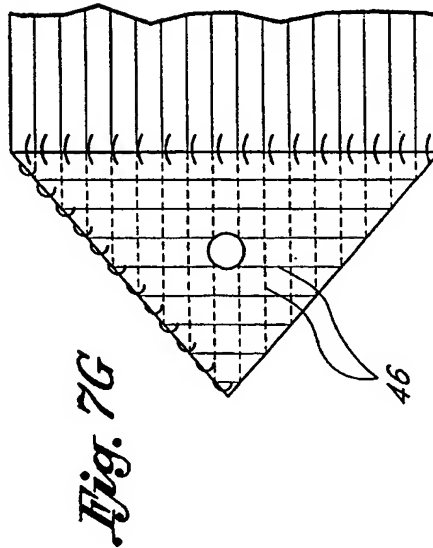


Fig. 7D

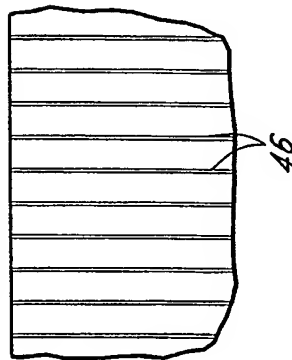


Fig. 7E

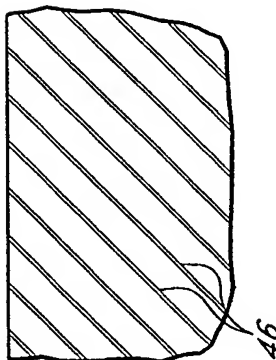


Fig. 8A

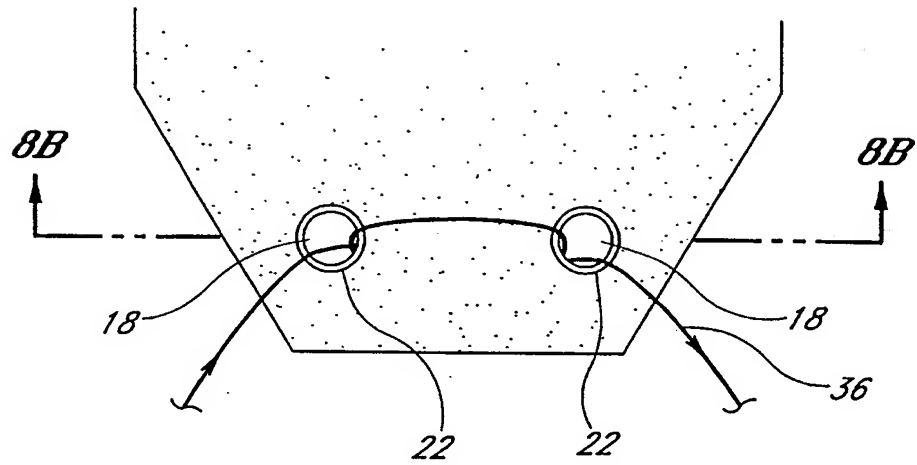


Fig. 8B

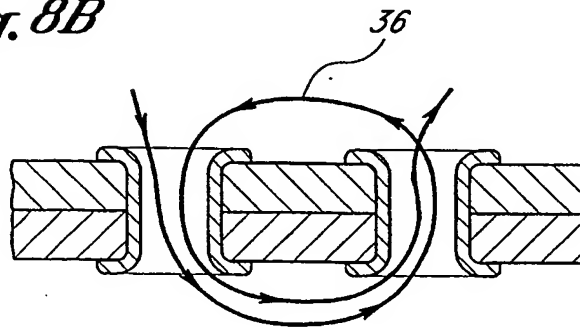


Fig. 8C

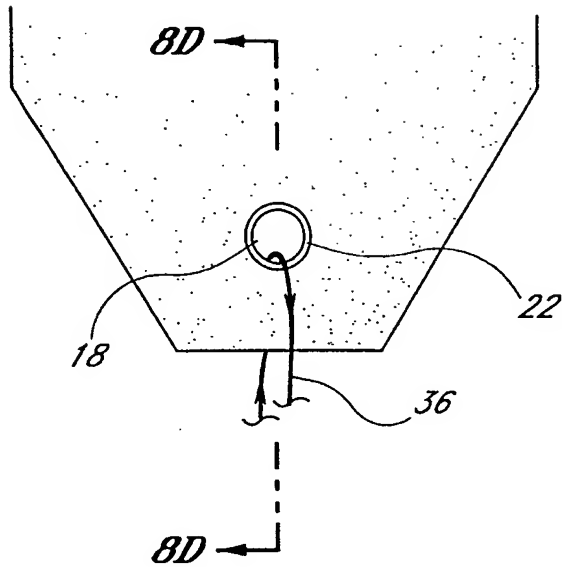


Fig. 8D

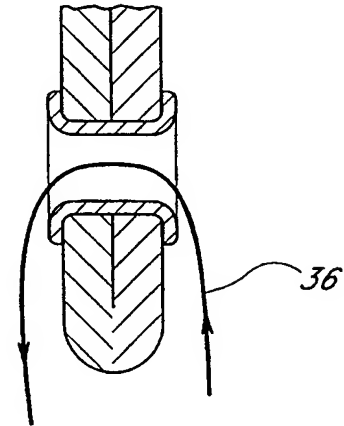


Fig. 8E

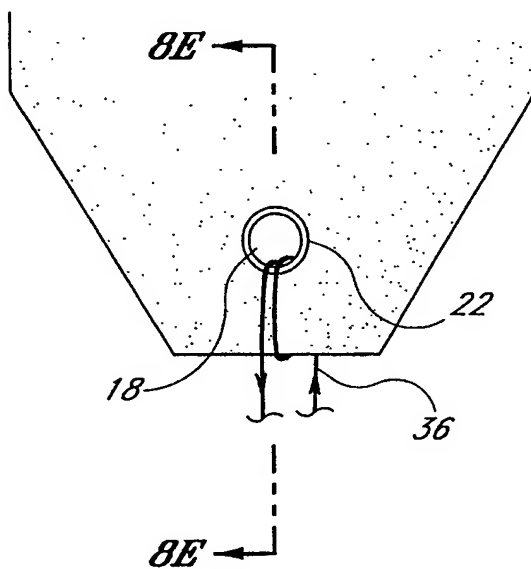


Fig. 8F

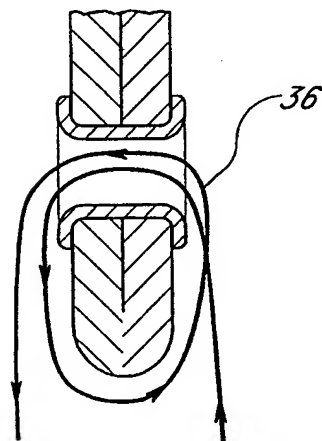


Fig. 9A

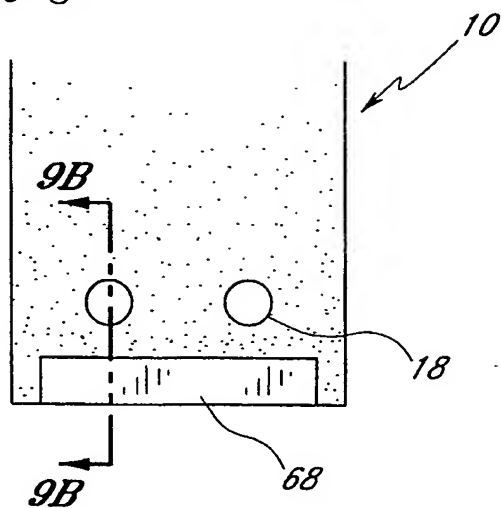


Fig. 9B

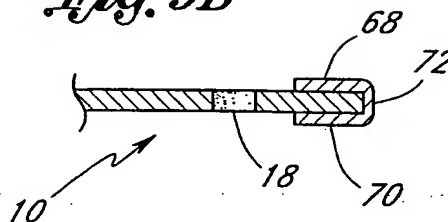


Fig. 9C

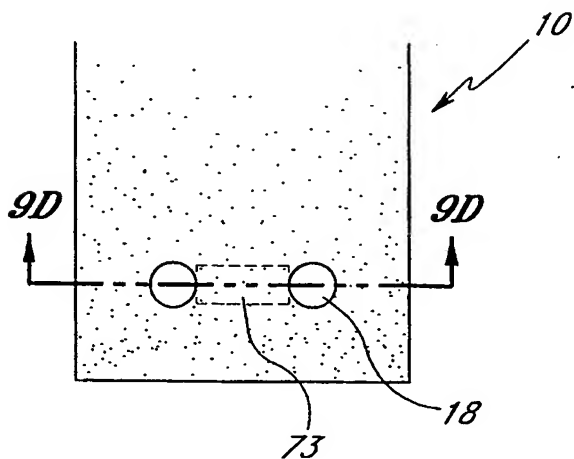
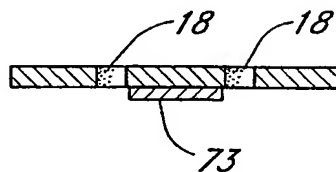


Fig. 9D



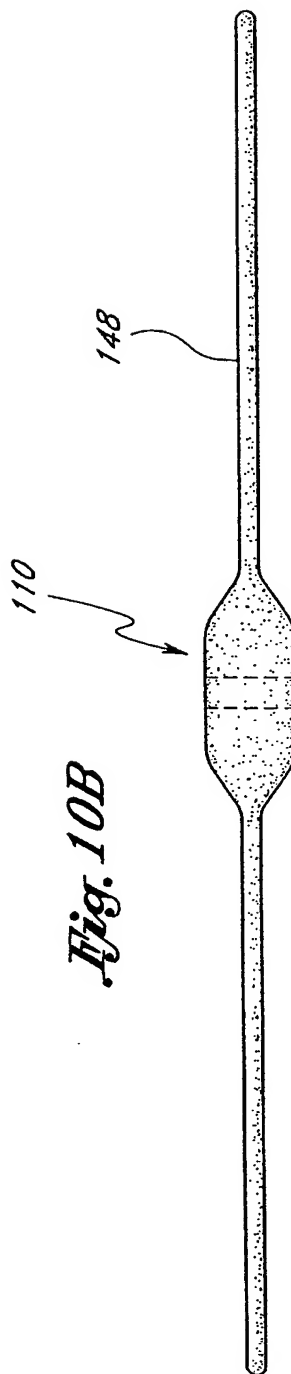
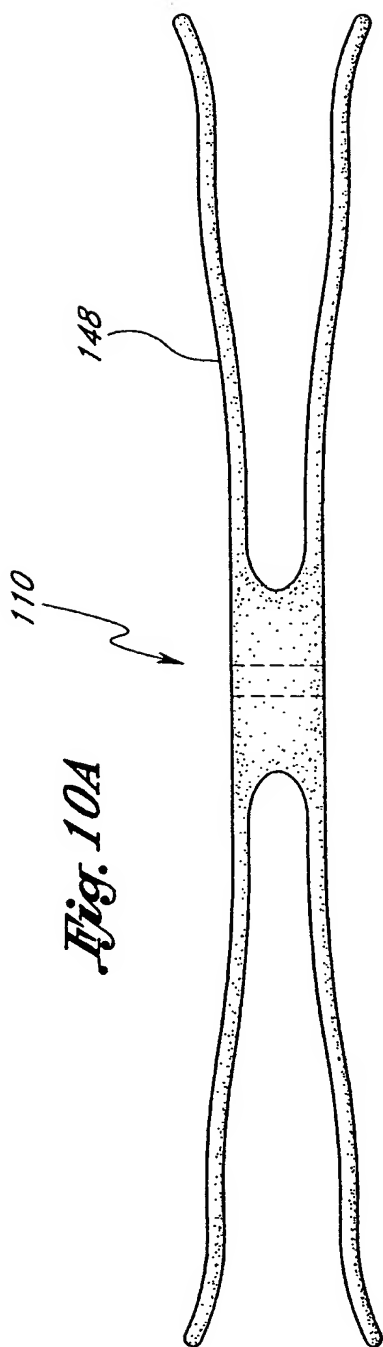


Fig. 11

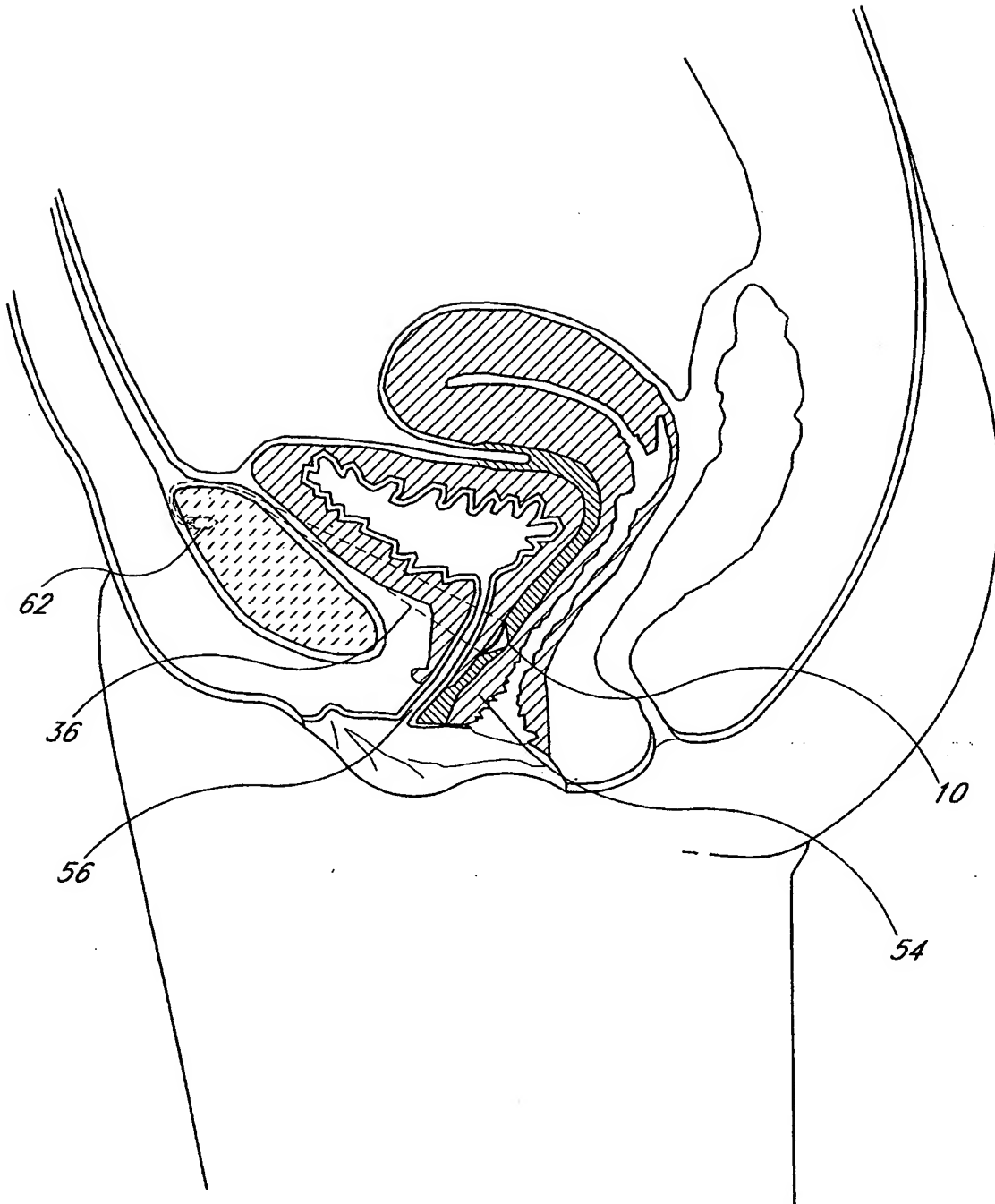


Fig. 12

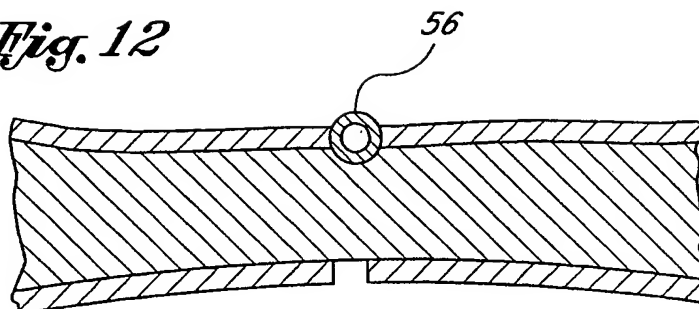


Fig. 13

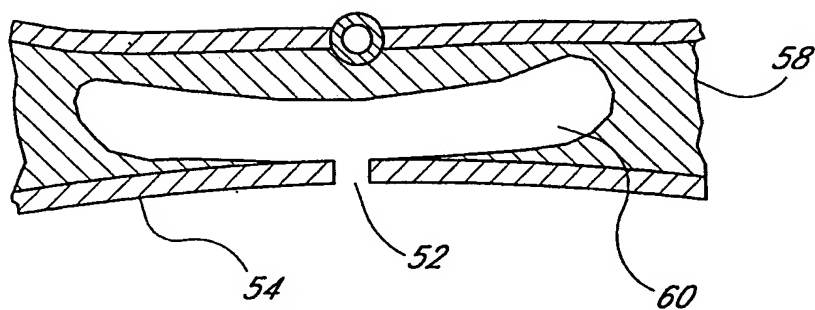
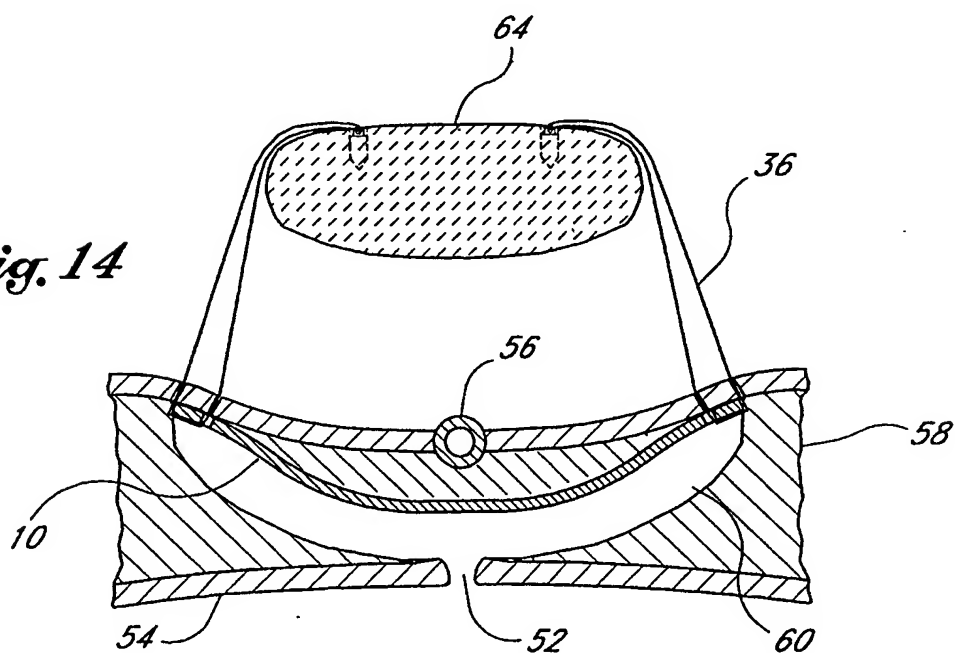


Fig. 14



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/03066

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61F 2/02

US CL : 600/030

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/DIG. 25; 600/29, 30; 606/232, 233; 623/12, 14, 16

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,527,341 A (GOGOLEWSKI et al) 18 June 1996, entire document.	1-3, 5, 21-25 ----- 4, 6-15, 18-20, 26-33
Y	JP 6-114067 A (SHIKINAMI) 26 April 1994, Abstract.	6, 9
Y	US 5,451,235 A (LOCK et al) 19 September 1995, col. 8 lines 55-60.	16, 17
X --- Y	US 5,013,292 A (LEMAY) 07 May 1991, col. 1 line 44 to col. 2 line 48.	22-25 ----- 34-36

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
B earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*A* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

15 APRIL 1998

Date of mailing of the international search report

28 MAY 1998

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

ROSALIND KEARNEY

Telephone No. (703) 308-2711

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US98/03066

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT.

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y, P	US 5,611,515 A (BENDEREV et al) 18 March 1997, col. 29 line 64 to col. 30 line 4.	34-36

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☒ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.

THIS PAGE BLANK (USPTO)